Review of Current FDA Guidance

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Disclaimers

- The information provided on the following pages is not intended to represent an all-inclusive list of guidance documents pertinent to the manufacture and use of molecular methods in immunohematology.
- Some guidances are included only to provide information regarding FDA's current considerations in regards to the areas mentioned.
- Some pertinent guidances may have been unintentionally omitted.

Home Pages

- CBER
- http://www.fda.gov/cber/
- CDRH Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)
- http://www.fda.gov/cdrh/oivd/index.html
  - IVD Guidances
  - IVD Standards
- CDRH “Device Advice”
- http://www.fda.gov/cdrh/devadvice/
- Device User Fees/MDUFMA
- http://www.fda.gov/cdrh/mdufma/index.html

For Immunohematology Reagents

- Recommended Methods for Blood Grouping Reagents Evaluation, March 1992 (Draft) 84S-0181
- Recommended Methods for Anti-Human Globulin Evaluation, March 1992 (Draft) 84S-0182
- Points to Consider in the Design and Implementation of Field Trials for Blood Grouping Reagents and Anti-Human Globulin, 1992 (Draft) 91N-0467

For Immunohematology Reagents

- **Guidance for Industry Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Biological *In Vitro* Diagnostic Products, March 1999**
  http://www.fda.gov/cber/gdlns/cmcbivd.htm

Molecular Tests

- **Class II Special Controls Guidance Document: RNA Preanalytical Systems (RNA Collection, Stabilization and Purification Systems for RT-PCR used in Molecular Diagnostic Testing), August 25, 2005**
  http://www.fda.gov/cdrh/oivd/guidance/1563.html

Molecular Tests

- **Draft Guidance for Industry and FDA Staff - Pharmacogenetic Tests and Genetic Tests for Heritable Markers, February 9, 2006**
  http://www.fda.gov/cdrh/oivd/guidance/1549.html

Molecular Tests

- **Drug Metabolizing Enzyme Genotyping System - Class II Special Controls Guidance Document - Guidance for Industry and FDA Staff, March 10, 2005**
  http://www.fda.gov/cdrh/oivd/guidance/1551.html

- **Nucleic Acid Based In Vitro Diagnostic Devices for Detection of Microbial Pathogens - Draft Guidance for Industry and FDA Staff, December 8, 2005**
  http://www.fda.gov/cdrh/oivd/guidance/1560.html

Molecular Tests

- **CFTR Gene Mutation Detection Systems - Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document, October 26, 2005**
  http://www.fda.gov/cdrh/oivd/guidance/1564.html

- **Class II Special Controls Guidance Document: Factor V Leiden DNA Mutation Detection Systems - Guidance for Industry and FDA Staff, March 16, 2004**
  http://www.fda.gov/cdrh/oivd/guidance/1236.html

Molecular Tests

- **Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Automated Fluorescence in situ Hybridization (FISH) Enumeration Systems, March 23, 2005**

  http://www.fda.gov/cdrh/oivd/guidance/1550.html

Biotechnology

- **Points to Consider in the Production and Testing of New Drugs and Biologicals Produced by Recombinant DNA Technology, April 10, 1985**
  http://www.fda.gov/cber/gdlns/ptcdna.htm

- **Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals, July 12, 1993**
  http://www.fda.gov/cber/guidelines.htm

General IVD Guidance

- **Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use, November 30, 2004**
- **http://www.fda.gov/cdrh/ocd/guidance/4444.html**

Statistics

- **Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests; Draft Guidance for Industry and FDA Reviewers, March 12, 2003**
- **http://www.fda.gov/cdrh/osb/guidance/1428.html**

Informed Consent (documents)

- **Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable - Guidance for Sponsors, Institutional Review Boards, Clinical Investigators and FDA Staff April 25, 2006**
- **http://www.fda.gov/cdrh/oivd/guidance/1588.html**

Informed Consent (documents)

- **A Guide to Informed Consent**
  http://www.fda.gov/oc/ohrt/IRBS/informedconsent.html

- **Frequently Asked Questions on Informed Consent Process and Informed Consent Document Content**
  http://www.fda.gov/oc/ohrt/IRBS/faqs.html

- **Declaration of Helsinki (World Medical Association's recommendations to every physician in biomedical research involving human subjects)**
  http://www.fda.gov/oc/health/helsinki89.html

Informed Consent (documents)

- **The Belmont Report, April 18, 1979**
  http://www.fda.gov/oc/ohrt/irbs/belmont.html

- **Significant Differences in FDA and HHS Regulations for Protection of Human Subjects**
  http://www.fda.gov/oc/ohrt/irbs/appendixe.html

- **Guidance on IDE Policies and Procedures**
  Text-http://www.fda.gov/cdrh/ode/idepolcy.html
  PDF-http://www.fda.gov/cdrh/ode/idepolcy.pdf

Informed Consent (web pages)

- **Information Sheet Guidances, Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors**
  http://www.fda.gov/oc/ohrt/irbs/default.htm

- **Information for Health Professionals - Clinical Trials and Institutional Review Boards**
  http://www.fda.gov/oc/oha/default.htm#clinical

- **Institutional Review Board Guidebook, 1993, National Institutes of Health, Office of Extramural Research, Office for Protection from Research Risks**
  http://ohrp.osophs.dhhs.gov/irb/irb_guidebook.htm

Clinical/Field Trials

- **Guidance for Industry, Acceptance of Foreign Clinical Studies, March 2001**
  http://www.fda.gov/cber/gdlns/clinical031301.htm

- **Guidance, Financial Disclosure by Clinical Investigators, March 20, 2001**
  http://www.fda.gov/oc/guidance/financialdis.html

- **Guidance for Industry, Computerized Systems Used in Clinical Trials, September 2004**
  http://www.fda.gov/cber/gdlns/compclintrial.htm

Instrumentation

- **Instrumentation for Clinical Multiplex Test Systems - Class II Special Controls Guidance Document - Guidance for Industry and FDA Staff, March 10, 2005**
  http://www.fda.gov/cdrh/oivd/guidance/1546.html

Software Contained in Medical Devices

- **Guidance for Industry and FDA Staff; Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005**
  http://www.fda.gov/cdrh/ode/guidance/337.html

- **Guidance for Off-the-Shelf Software Use in Medical Devices; Final, September 9, 1999**
  http://www.fda.gov/cdrh/ode/guidance/585.html

Products in Development

- **Commercialization of In Vitro Diagnostic Devices (IVD's) Labeled for Research Use Only or Investigational Use Only – Draft, January 5, 1998**
  http://www.fda.gov/cdrh/comp/ivddrfg.html

"Home Brew"

- **Draft Guidance for Industry and FDA Staff - Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions, September 7, 2006**
  http://www.fda.gov/cdrh/oivd/guidance/1590.html

- **Draft Guidance for Industry, Clinical Laboratories, and FDA Staff - In Vitro Diagnostic Multivariate Index Assays, September 7, 2006**
  http://www.fda.gov/cdrh/oivd/guidance/1610.html

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- **http://www.fda.gov/cdrh/subscribe.html**